IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI and SANOFI-AVENTIS U.S. LLC	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No.: _____
	)	
FIRST TIME US GENERICS LLC	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendant First Time US Generics LLC ("FTUG" or "Defendant") hereby allege as follows:

THE PARTIES

1. Plaintiff Sanofi is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

2. Plaintiff Sanofi U.S. is a wholly owned U.S. subsidiary of Sanofi and is a company organized and existing under the laws of the state of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. On information and belief, defendant FTUG is a limited liability company organized and existing under the laws of the state of Florida, having a principal place of business located at 505 Park Way, Suite 6, Broomall, PA 19008.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code and for a declaratory judgment of patent infringement arising under the Declaratory

Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

5. This Court has personal jurisdiction over FTUG. On information and belief, FTUG regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that FTUG has continuous and systematic contacts with Delaware.

6. On information and belief, FTUG directly or through its affiliates and agents, formulates, manufactures, packages, markets, and/or sells drug products throughout the United States and in this judicial district.

7. On information and belief, upon approval of FTUG's Abbreviated New Drug Application (ANDA) No. 205745, FTUG or its affiliates and agents will market and sell FTUG's Dronedarone Hydrochloride Tablets Eq 400 mg base ("FTUG's Proposed Generic Product") in Delaware and throughout the United States and FTUG will derive substantial revenue therefrom.

8. On information and belief, upon approval of FTUG's ANDA, FTUG or its affiliates or agents will place FTUG's Proposed Generic Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will ultimately be purchased and used by consumers in this judicial district.

9. FTUG is currently engaged in an action against Sanofi in the District of Delaware, namely *Sanofi et al. v. Glenmark Pharmaceuticals, Inc. USA, et al.*, Civil Action No. 14-264 (D. Del.), and has availed itself of this forum by consenting to personal jurisdiction and asserting counterclaims in that action.

10. On information and belief, FTUG has previously availed itself of this forum by submitting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction including, for example, *Forest Labs., Inc. et al. v. First Time US Generics LLC* (1:13-cv-01642).

11. On information and belief, this Court further has personal jurisdiction over FTUG because FTUG regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware and committed the tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to plaintiff Sanofi U.S., a Delaware corporation.

12. This Court has personal jurisdiction over FTUG by virtue of, *inter alia*, the above-mentioned facts.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b).

THE PATENTS-IN-SUIT

14. Sanofi U.S. holds approved New Drug Application ("NDA") No. 022425 for dronedarone tablets, 400 mg, which are prescribed and sold in the United States under the trademark Multaq®. The U.S. Food and Drug Administration ("FDA") approved NDA No. 022425 on July 1, 2009. Multaq® tablets are indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

15. United States Patent No. 9,107,900 ("the '900 patent," copy attached as Exhibit A) is entitled "Use of Dronedarone for the Preparation of a Medicament for Use in the

Prevention of Cardiovascular Hospitalization or of Morality [sic]" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on August 18, 2015. The '900 patent claims, *inter alia*, methods of using dronedarone. The '900 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Multaq® tablets (NDA No. 022425).

16. The named inventors on the '900 patent are Davide Radzik, Martin Van Eickels, Nacera Hamdani, and Christophe Gaudin. The '900 patent is assigned to Sanofi.

17. According to the Orange Book, the '900 patent expires on April 16, 2029.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

18. FTUG submitted ANDA No. 205745 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of FTUG's Proposed Generic Product.

19. On information and belief, ANDA No. 205745 seeks FDA approval of FTUG's Proposed Generic Product for the indication of reducing the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

20. By letters dated January 30, 2014 and March 20, 2014, and pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c), FTUG notified Plaintiffs that it had submitted ANDA No. 205745 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of FTUG's Proposed Generic Product before the expiration of several Sanofi patents listed in the Orange Book for Multaq® tablets, including U.S. Patent No. 8,318,800 ("the '800 patent") and U.S Patent No. 8,410,167 ("the '167 patent").

21. According to the Orange Book, the ’800 patent expires on June 19, 2018 and the ’167 patent expires on April 16, 2029.

22. In its letters, FTUG notified Plaintiffs that, as a part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”) with respect to the ’800 patent and the ’167 patent. On information and belief, FTUG certified that, in its opinion and to the best of its knowledge, the ’800 patent and the ’167 patent are invalid and/or will not be infringed by the manufacture, use, or sale of FTUG’s Proposed Generic Product.

23. On March 6, 2014, Sanofi sued First Time in the District of Delaware for, *inter alia*, infringement of the ’800 patent and the ’167 patent pursuant to 35 U.S.C. §271(e)(2). That infringement action has been consolidated with other related litigations in *Sanofi et al. v. Glenmark Pharmaceuticals Inc., USA, et al.*, 14-264-RGA (D. Del.).

24. On information and belief, FTUG’s ANDA does not contain a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV) for the ’900 patent.

25. Pursuant to 21 U.S.C. § 355(j) and 21 C.F.R. § 314.94, FTUG is required to make a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV) to the ’900 patent.

26. On information and belief, based upon, *inter alia*, FTUG’s Paragraph IV certifications to the earlier-expiring ’800 patent, FTUG is seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of FTUG’s Proposed Generic Product before the expiration of the ’900 patent.

COUNT I
Infringement of U.S. Patent No. 9,107,900 Under 35 U.S.C. §271(e)(2)

27. Plaintiffs repeat and reallege paragraphs 1 through 26 as if fully set forth herein.

28. By submitting ANDA No. 205745 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of FTUG's Proposed Generic Product throughout the United States prior to the expiration of the '900 patent, FTUG committed an act of infringement of the '900 patent under 35 U.S.C. §271(e)(2).

29. The commercial manufacture, use, offer for sale, sale, and/or importation of FTUG's Proposed Generic Product, for which FTUG seeks approval in ANDA No. 205745, will induce infringement of or more claims of the '900 patent under 35 U.S.C. § 271(b). Specifically, the product label and medication guide that will be included with FTUG's Proposed Generic Product, if sold, will encourage, recommend, and/or promote the practice of one or more claims of the '900 patent.

30. Plaintiffs will be irreparably harmed by FTUG's infringing activities and do not have an adequate remedy at law.

COUNT II
Declaratory Judgment of Infringement of
U.S. Patent No. 9,107,900 Under 35 U.S.C. §271(b)

31. Plaintiffs repeat and reallege paragraphs 1 through 30 as if fully set forth herein.

32. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

33. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution and this actual case or controversy requires a declaration of rights by this Court.

34. FTUG has made and will continue to make substantial preparation in the United Sates to manufacture, sell, offer to sell, and/or import FTUG's Proposed Generic Product prior to the expiration of the '900 patent.

35. FTUG's actions, including but not limited to filing, maintaining, and not withdrawing ANDA No. 205745 containing Paragraph IV Certifications to the '800 patent and the '167 patent, evince a refusal to change its course of action in the face of acts by Plaintiffs, including but not limited to Plaintiffs' listing of the '900 patent in the Orange Book.

36. The commercial manufacture, use, offer for sale, sale, and/or importation of FTUG's Proposed Generic Product, for which FTUG seeks approval in ANDA No. 205745, will induce infringement of one or more claims of the '900 patent under 35 U.S.C. §§ 271(b). Specifically, the product label and medication guide that will be included with FTUG's Proposed Generic Product, if sold, will encourage, recommend, and/or promote the practice of one or more claims of the '900 patent.

37. Plaintiffs are entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and/or importation of FTUG's Proposed Generic Product prior to the expiration of the '900 patent will constitute inducement of infringement of the '900 patent.

38. Plaintiffs will be irreparably harmed by FTUG's infringing activities and do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against defendant FTUG and respectfully request the following relief:

A. A judgment that under 35 U.S.C. § 271(e)(2)(A), FTUG has infringed one or more claims of the ’900 patent by submitting ANDA No. 205745 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of FTUG’s Proposed Generic Product before the expiration of the ’900 patent;

B. A judgment that the manufacture, use, offer for sale, sale, and/or importation of FTUG’s Proposed Generic Product will infringe the ’900 patent;

C. A declaration under 28 U.S.C. § 2201 that if FTUG and/or its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of FTUG’s Proposed Generic Product prior to the expiration of the ’900 patent, it will constitute an act of infringement of the ’900 patent.

D. A judgment declaring that the ’900 patent remains valid and enforceable;

E. A permanent injunction restraining and enjoining FTUG and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of FTUG’s Proposed Generic Product until the expiration of the ’900 patent or any later date of exclusivity to which Plaintiffs are or become entitled.

F. An order that the effective date of any approval of FTUG’s ANDA No. 205745 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration of the ’900 patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

G. A determination that this case is “exceptional” under 35 U.S.C. § 285 and an award of attorneys’ fees;

H. Costs and expenses in this action; and

I. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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